K014158

MAR 1 4 2002

510(K) SUMMARY
Endoscopic Camera TC804/C4

I. Submitter:

WORLD OF MEDICINE Lemke GmbH
Danziger Strasse 21
82194 Groebenzell
Germany

II. Device Names:

1.	Classification Name:	Accessory to an Endoscope
2.	Common or Usual Name:	Endoscopic Camera
3.	Proprietary Name:	Endoscopic Camera TC804/C4

III. Classification:

Class II. This device is described in 21 C.F.R. § 876.1500. The product code for the device is GCJ.

IV. Predicate Devices:

- Karl Storz Endovision Tricam, Model 20221101 (202) (K950862)
- Circon MicroDigital IP 6.2 (K914883) surgi mkt.s
- Image Technologies SteriCam, Coupler-Drape and TrowView Imaging System (K983567)

V. Intended Use:

The Endoscopic Camera TC804/C4 is intended to attach to standard endoscopes to permit visualization of body cavities, hollow organs and canals during endoscopic procedures. It also may be attached to a microscope. The endoscopic image can be displayed on any standard video monitor.

VI. Device Description:

The Endoscopic Camera TC804/C4 is a 3-CCD camera, which consists of a camera control unit (CCU), a camera head, various connecting objectives, cables and adapters. The Endoscopic Camera TC804/C4 takes the image through standard endoscopes that would be normally seen with the naked eye, and displays it on any standard video monitor. The camera head is supplied with a standard 30 mm endofocus objective but may also be used with a 25 mm or zoom objective. The device is programmable by two head key bottons and is equipped with a ring-focus for both right-handed and left-handed users.

VII. Substantial Equivalence:

The Endoscopic Camera TC804/C4 described in this notification is similar in design and construction to the **Endovision Tricam, Model 20221101 (202)** (K950862) manufactured by Karl Storz Imaging, Inc., the **MicroDigital IP 6.2** (K914883) manufactured by Circon Corporation and the device **Image Technologies SteriCam, Coupler-Drape and TrowView Imaging System** (K983567).

The Endoscopic Camera TC804/C4 and the predicate devices are all intended to permit visualization of body cavities, hollow organs and canals during endoscopic procedures. The camera head of the Endoscopic Camera TC804/C4 and the predicate devices is designed to attach to standard, commercially available, endoscopes and the endoscopic image in the proposed and predicate devices can be displayed on any standard video monitor.

The differences between the proposed and predicate devices are limited to picture quality and handling convenience.

Accordingly, WORLD OF MEDICINE Lemke GmbH believes that the proposed new device, the Endoscopic Camera TC804/C4, is substantially equivalent to the predicate devices currently on the market.

VIII. Performance Data:

The Endoscopic Camera TC804/C4 complies with the International Standard IEC 601-1, IEC 601-1-2, the European Standard EN 55011 and conforms to the Medical Device Directive 93/42 EEC. The device will be tested in accordance with UL2601-1.

Signed: S. Raab

Susanne Raab
Official Correspondent

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 1 4 2002

World of Medicine Lemke GMBH
c/o Susanne Raab
Regulatory Consultant
91 Trowbridge Street
Cambridge, Massachusetts 02138

Re: K014158
Trade Name: Endoscopic Camera TC804/C4
Regulation Number: 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: GCJ
Dated: December 17, 2001
Received: December 19, 2001

Dear Ms. Raab:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

STATEMENT OF INDICATIONS FOR USE

APPLICANT: WORLD OF MEDICINE Lemke GmbH

510(K) NUMBER (if known): K014158

DEVICE NAME: Endoscopic Camera TC804/C4

INDICATIONS FOR USE:

The Endoscopic Camera TC804/C4 is intended to attach to standard endoscopes to permit visualization of body cavities, hollow organs and canals during endoscopic procedures. It also may be attached to a microscope. The endoscopic image can be displayed on any standard video monitor.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Per 21 C.F.R. § 801.109)

(Optional Format 1-2-96)

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K014158